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07/835,964 02/20/92 COATES

EXAMINER A

12M2/0809

EXAMINER UNIT PAPER NUMBER

JAMES F. HALEY, JR.
FISH & NEAVE
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50TH FLOOR

DATE MAILED:

NEW YORK, NY 10020
This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

08/09/94

☐ This application has been examined ☒ Responsive to communication filed on 7/25/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 3-5, 7, 10, 21 and 22 are pending in the application.
Of the above, claims — are withdrawn from consideration.
2. ☒ Claims 1, 2, 6, 8, 9, 11-20 have been cancelled.
3. ☐ Claims — are allowed.
4. ☒ Claims 3-5, 7, 10, 21 and 22 are rejected.
5. ☐ Claims — are objected to.
6. ☐ Claims — are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on —. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on —, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed —, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☐ been filed in parent application, serial no. —; filed on —.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-328 (Rev. 2/93)

Art Unit 1202

Claims 3-5, 10, 21 and 22 are pending. The history of the application, 1.132 declaration, references of record and case law cited have been reviewed.

Claims 3-5, ⁷10, 21 and 22 are rejected under 35 USC 102 and 103 over EP '526 and US '407. *Eli Lilly & Co. v. Generic Drug Sales*, 169 USPQ 13 cited previously is in point (see paper 12). Applicants urged that *Eli Lilly & Co. v. Generic Drug Sales* relates to the issue of patent infringement, and it does not address the issue of the patentability. The decision of that case is that alpha-d form of propoxyphene hydrochloride would constitute an infringement of claim 2 of US '779, which is the racemic mixture. If alpha-d form is patentable, then it would not constitute an infringement. The case law also states (page 15, item 12) that it is common knowledge that optical isomers of a chemical compound frequently differ in their pharmacological action. Instant compound possesses two centers of asymmetry and, therefore, occurs in two pairs of mirror image forms. Therefore, it is routine to find out which one contributes the activity. EP and US also implicitly and inherently made available the four enantiomers. (Cf *Eli Lilly & Co. Inc. v.*

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Generic Drug Sales, Inc. p. 15). The finding of nonnatural (-)-enantiomer is as active as the natural (+)-enantiomer is surprising. But the routine to find out which one of the four enantiomers contribute the activity is not "obvious to experiment".

Claims remain rejected under 35 USC 103 and 102 over US '466 for the reasons of record.

In view of Ex parte Balzarini 21 USPQ 2d 1892, the in vitro tests are not predictive of in vivo efficacy. Applicant is invited to submit clinical data since the compound is on clinical trial. Finality is withdrawal since new rejection is made.

A facsimile center has been established in Group 1200, room 3C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or 305-3592.

Serial No. 07/835,964

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Any inquiry concerning this communication should be directed to
Examiner Tsang at telephone number (703) 308-4715.

Tsang: ach
August 05, 1994

C Tsang
CECILIA TSANG
PRIMARY EXAMINER
GROUP 1200